

**REMARKS**

The pending Office Action addresses and rejects claims 1-9, 11-17, 20, and 21.  
Reconsideration and allowance is respectfully requested in view of the following remarks.

***Amendments to the Claims***

Applicants amend claim 1 to recite that the bioabsorbable sheath expander is configured “to deform the concave outer surface of the sidewalls toward a circular geometry.” Support for this amendment can be found throughout the specification, for example, at paragraph [0029]. No new matter is added.

***Rejection Pursuant to 35 U.S.C. §102***

The Examiner rejects claims 1, 2, 5-7, and 11-17 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Publication No. 2002/0007182 of Kim (“Kim”). Applicants respectfully disagree.

**Claims 1-9**

Independent claim 1, as amended, recites a graft fixation device including a bioabsorbable radially expandable sheath and a bioabsorbable sheath expander. The sheath has a slot-free distal tip and at least two sidewalls that extend proximally therefrom and define a central lumen. Each sidewall has a substantially concave outer surface adapted to seat a graft member. The expander is adapted to be disposed in the central lumen of the sheath and is configured to deform the concave outer surface of the sidewalls toward a circular geometry.

Kim fails to teach or even suggest an expander that is adapted to deform a concave outer surface of a sheath toward a circular geometry. Kim discloses an anchor (10) having a generally bullet-like configuration with a slit extending along the length of the anchor (10) to form a pair of legs (18, 20). The legs (18, 20) have a substantially triangular cross-section that includes a base, two sides, and an apex. As shown in FIG. 3 of Kim, the base forms an outer convex surface, and the sides form concave recesses (19, 21). Kim also discloses a wedge (48) that can be inserted and lodged between the anchor’s legs. As explained by Kim at paragraph [0042], “[t]he wedge serves to force or spread the legs outward and further force the anchoring thereof tightly in the tunnels in the femur.” In other words, the wedge (48) forces the outer *convex surface* of the legs

(18, 20) against the bone tunnel. The wedge disclosed by Kim does not act upon the concave recesses (19, 21) – much less deform the concave recesses (19, 21) toward a circular geometry, as required by independent claim 1. Moreover, the configuration of the wedge (48) (i.e., it is triangular in shape and sized to fit between the legs of the anchor) is such that it could not deform the concave recesses (19, 21) of the legs (18, 20) toward a circular geometry. Accordingly, independent claim 1, as well as claims 2-9 which depend directly or indirectly therefrom, distinguish over Kim and represent allowable subject matter.

Claims 11-17 and 20-21

Independent claim 11 recites a graft fixation kit including a bioabsorbable expandable sheath and a *plurality* of sheath expanders of *varying sizes*. In order to anticipate a claim, the prior art must teach each and every limitation of the claim. Kim fails to disclose a plurality of sheath expanders of varying sizes. Kim merely discloses one size wedge (48) and does not teach or even suggest that expanders of varying sizes can be used with a single expandable sheath, as required by claim 11. Accordingly, independent claim 11, as well as claims 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Kim and represent allowable subject matter.

***Rejections Pursuant to 35 U.S.C. §103***

U.S. Patent 5,632,748 of Beck, Jr. et al.

The Examiner rejects claims 11-13 and 15-17 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent 5,632,748 of Beck, Jr. et al. (“Beck”). The Examiner asserts that Beck teaches the claimed invention except for a “bioabsorbable” sheath expander. The Examiner argues that it would have been obvious “to have used a biodegradable expander with the invention of Beck, Jr. et al., since it has been held to be within the general skill of a worker in the art to select a know material.” Applicants respectfully disagree.

As noted above, independent claim 11 recites a graft fixation kit including a bioabsorbable expandable sheath and a plurality of sheath expanders of varying sizes. Beck fails to disclose a kit including a plurality of sheath expanders of varying sizes. Beck teaches an anchor member (416) and an insertion member (28). Beck merely discloses one size insertion member (28) and does not teach or even suggest that expanders of varying sizes can be used with a single expandable sheath, as required by claim 11. Accordingly, independent claim 11, as well

as claims 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Beck and represent allowable subject matter.

U.S. Publication 2001/0007074 of Strobel et al.

The Examiner rejects claims 1-3, 11-13, 20, and 21 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Publication 2001/0007074 of Strobel et al. ("Strobel"). The Examiner asserts that Strobel teaches the claimed invention except for a "bioabsorbable" sheath expander. The Examiner argues that it would have been obvious "to have used a biodegradable expander with the invention of Strobel, et al., since it has been held to be within the general skill of a worker in the art to select a know material." Applicants respectfully disagree.

Strobel fails to teach or even suggest an expandable sheath, as required by claims 1 and 11, much less a kit including a expandable sheath and a plurality of sheath expanders of varying sizes, as further required by claim 11. Strobel merely discloses a screw (10) and a drive tool (40). The screw (10) is not expandable, and the drive tool (10) is merely a driver that is configured to drive the screw into bone – not to deform the screw. Accordingly, independent claims 1 and 11, as well as claims 2-9 and 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Strobel and represent allowable subject matter.

WO 02/32345 of Jacobs, et al.

The Examiner rejects claims 1-4, 8, 9, 11-14, 20, and 21 pursuant to 35 U.S.C. §103(a) as being obvious over WO 02/32345 of Jacobs, et al. ("Jacobs"). The Examiner asserts that Jacobs teaches the claimed invention except for a "bioabsorbable" sheath expander. The Examiner argues that it would have been obvious "to have used a biodegradable expander with the invention of Jacobs, et al., since it has been held to be within the general skill of a worker in the art to select a know material." Applicants respectfully disagree.

Jacobs fails to teach or even suggest a sheath expander, much less an expander that is configured to deform a concave outer surface of a sheath toward a circular geometry, as required by claim 1. As acknowledged by the Examiner on pg. 6 of the Office Action, Jacobs does not explicitly disclose an "expander." The Examiner asserts that the insertion tool (184) is equivalent to the expander recited in claim 1. Assuming, for the sake of argument, that the insertion tool or pin (184) is an expander, the pin (184) does not deform a concave outer surface of the sheath toward a circular geometry, as required by claim 1. As shown in FIGS. 4C and 4D and explained

at pg. 11, line 24 through pg. 12, line 2 of Jacobs, the pin (184) merely acts against rotating barbs (182) to cause them to dig into an interior surface of a bone tunnel. The pin (184) does not deform the barbs (182) toward a circular geometry nor could it, as the rotating barbs (182) are *hinged* to the device (180) such that they are allowed to rotate with respect to the device. Accordingly, independent claim 1, as well as claims 2-9 which depend directly or indirectly therefrom, distinguish over Jacobs and represent allowable subject matter.

Jacobs also fails to disclose a kit including a plurality of sheath expanders of varying sizes, as required by claim 11. Jacobs merely discloses one size pin (184) and does not teach or even suggest that expanders of varying sizes can be used with a single expandable sheath, as required by claim 11. Accordingly, independent claim 11, as well as claims 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Jacobs and represent allowable subject matter.

WO 02/32345 of Jacobs, et al. and U.S. Publication 2002/0072797 of Hays, et al.

The Examiner rejects claims 5-7 and 15-17 pursuant to 35 U.S.C. §103(a) as being obvious over Jacobs in view of U.S. Publication 2002/0072797 of Hays, et al. ("Hays") now U.S. Patent 6,554,862. The Examiner asserts that Jacobs discloses the claimed invention except for the "stop member at a proximal end of the sheath" and "the expander as a tapered screw." The Examiner relies on Hays to teach these features arguing that it would have been obvious to combine the device of Jacobs with Hays to reach the claimed invention. Applicants respectfully disagree.

As explained above, Jacobs fails to teach or even suggest a sheath expander, as required by independent claims 1 and 11. One having ordinary skill in the art would have no motivation to modify the device of Jacobs to include an expander as taught by Hays. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP §2144). There is no advantage to modifying the anchor device (180) of Jacobs to include a sheath expander as taught by Hays because Jacobs already discloses features specifically designed to secure the anchor (180) in a bone tunnel. As explained at pg. 11, line 11 through pg. 12, line 3, radial protuberances or barbs (182) on the anchor device (180) are "mechanically deployed using a pin (184) (as shown in Figure 4D) after the device (180) and its attendant soft tissue are placed in the crafted hole in the boneface." Jacobs goes on to explain that the deployed barbs (182) "dig into the interior of the crafted bone


hole and secure device (180) in place.” Since Jacobs specifically discloses a pin (184) to deploy the barbs (182) and secure the anchor device (180) in a bone tunnel, there is no need to modify Jacobs to include a separate sheath expander, as taught by Hays. Accordingly, independent claims 1 and 11, as well as claims 2-9 and 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Jacobs and Hays, taken alone or combined, and represent allowable subject matter.

***Conclusion***

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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Lisa Adams, Reg. No. 44,238  
Attorney for Applicant(s)

Nutter McClennen & Fish LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA 02210  
Tel: (617)439-2550  
Fax: (617)310-9550

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